THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 31

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte BRUCE A. GREEN
and GARY W. ZLOTNICK

Appeal No. 94-1618
Application 07/491,466[1]

ON BRIEF

Before McKELVEY, Chief Administrative Patent Judge and WINTERS and GRON, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision refusing to allow claims 47-57, 61-76, 88, and 90-94, which are all of the claims remaining in the application.

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[1] Application for patent filed March 9, 1990. According to applicant, the application is a continuation-in-part of Application 07/320,971, filed March 9, 1989.

THE CLAIMS

Claims 67 and 75 are representative:

67. A vaccine composition comprising an immunogenic amount of essentially pure protein "e" of Haemophilus influenzae in a pharmaceutically acceptable vehicle; wherein the protein elicits a protective immune response in a mammalian host.

75. A method of immunizing against Haemophilus influenzae, comprising administering to a mammalian host an immunogenic amount of essentially pure protein "e" of Haemophilus influenzae; wherein the protein elicits a protective immune response in the mammalian host.

THE REFERENCES

In rejecting all of the appealed claims under 35 USC 112, first paragraph, as based on a non-enabling disclosure, the examiner relies on the following references:

Munson et al. (Munson), Infection and Immunity, "Purification and Partial Characterization of Outer Membrane Proteins P5 and P6 from *Haemophilus influenzae* Type b", Vol. 49, No. 3, pages 544-549 (1985).

Granoff et al. (Granoff), The Journal of Infectious Diseases, "Prospects for Prevention of *Haemophilus influenzae* Type b Disease by Immunization", Vol. 153, No. 3, pages 448-461 (1986).

THE REJECTIONS

All of the appealed claims stand rejected under 35 USC 112, first paragraph, as based on a non-enabling disclosure. This rejection is set forth in the examiner's Answer, Paper No.

25, Section (10) entitled "New Ground of Rejection". According to the examiner, the disclosure is enabling only for claims reciting the specific steps described by appellants in their specification for purifying protein "e". The examiner asserts that none of the claims recite those steps and, accordingly, that all of the claims are vulnerable to rejection under Section 112, first paragraph.

All of the appealed claims further stand rejected under 35 USC 101 "because the claimed invention lacks patentable utility". This rejection is set forth in the Answer, pages 2 and 3. In a related rejection, all of the appealed claims stand rejected under 35 USC 112, first paragraph, as based on a specification which does not adequately teach "how to use" the claimed invention. See the examiner's Answer, page 4, lines 1-13.

Finally, the examiner's Answer clarifies what issues are not presented for review. As stated in the Answer, page 4, lines 14 and 15, "the rejection of the claims under 35 USC 103 is withdrawn in view of the arguments presented in the Brief".

DELIBERATIONS

Our deliberations in this matter have included evaluation and review of the following materials:

(1) The instant specification, including Figures 1-8, and all of the claims on appeal;

(2) The Barenkamp reference cited in the specification, page 22;

(3) Appellants' main Brief and Reply Brief before the Board;

(4) The article by Loeb cited at page 17 of appellants' main Brief, and attached to the Brief as Appendix II;

(5) The examiner's Answer and Supplemental Answer;

(6) The Munson et al. and Granoff et al. articles referred to in Section (10) of the Answer entitled "New Ground of Rejection";

(7) U.S. Patent Nos. 5,108,744 and 5,110,908, referred to in appellants' main Brief before the Board, page 11;

(8) The declaration of Green and Zlotnick filed under the provisions of 37 CFR 1.132, executed September 24, 1991; and

(9) The declaration of Dr. Arnold L. Smith, filed under the provisions of 37 CFR 1.132, executed November 3, 1989.

Having carefully considered those materials, we agree with appellants that the appealed claims are based on a fully enabling disclosure. We also agree that the specification sets forth a credible and patentable utility for the claimed invention, and that the specification adequately discloses "how

to use" the claimed invention. Accordingly, we shall not sustain the non-prior art rejections on appeal.

DISCUSSION

We first address the rejection of all the appealed claims under 35 USC 112, first paragraph, as based on a non-enabling disclosure. In setting forth this rejection, the examiner focuses on the claim limitation "essentially pure protein 'e'". According to the examiner, that limitation embraces proteins prepared by methods described in the above-cited references authored by Munson et al. or Granoff et al. "as well as other purification procedures". See the examiner's Answer, paragraph bridging pages 4 and 5. It follows, according to the examiner's logic and reasoning, that "essentially pure protein 'e'" embraces proteins which do not elicit a protective immune response in a mammalian host. In so finding, the examiner points out that (1) Munson et al. and Granoff et al. do not disclose proteins capable of eliciting a protective immune response in a mammalian host; and (2) in the main Brief before the Board, page 18, first paragraph, appellants state that they "were able to obtain purified protein 'e' [capable of eliciting a protective immune response in a mammalian host] because they used a novel differential detergent extraction procedure to purify protein 'e'" [emphasis added]. The examiner concludes that the

appealed claims are not enabled throughout their scope, and that appellants' disclosure is enabling only for claims reciting the specific steps described in the specification for purifying protein "e". We disagree with this line of reasoning.

The examiner is not at liberty to dissect the claims, to isolate a claim limitation, and to focus myopically on that limitation without considering other limitations in the claims or the claimed subject matter as a whole. On the contrary, every limitation in the claims must be given effect rather than considering one in isolation from the others. In re Geerdes, 491 F.2d 1260, 1262-63, 180 USPQ 789, 791 (CCPA 1974). Here, appellants' composition claims not only recite "essentially pure protein 'e'" but also define a vaccine containing that protein "wherein the protein elicits a protective immune response in a mammalian host". By the same token, the method claims require that the protein elicits a protective immune response in the mammalian host. Considering the claimed subject matter as a whole, we disagree with the finding that "essentially pure protein 'e'" embraces proteins which do not elicit a protective immune response in the mammalian host. By its very terms, the claim language contradicts such an interpretation. The literal terms of the claims before us require that "essentially pure protein 'e'" elicits a protective immune response in the mammalian host.

Furthermore, appellants' specification contains a fully enabling disclosure setting forth the steps required for purification of protein "e" so that the protein elicits a protective immune response in the mammalian host. It is the role of the specification to set forth such details, and the examiner erred by requiring that the claims recite appellants' purification steps. The claims as written are based on an enabling disclosure. The examiner's position to the contrary, notwithstanding, the claims as written cover essentially pure protein "e" wherein the protein elicits a protective immune response in the mammalian host, and do not cover or embrace proteins which do not elicit a protective immune response in the mammalian host. Compare In re Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976) (claims do not cover catalysts which do not work to produce the intended result). Accordingly, the rejection of all the appealed claims under 35 USC 112, first paragraph, as based on a non-enabling disclosure is reversed.

We next consider the rejections of all the appealed claims under 35 USC 101 and 35 USC 112, first paragraph, as based on a disclosure which does not describe a patentable utility for the claimed invention and does not adequately teach "how to use" the claimed invention. As stated in In re Langer, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974),

> As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

Likewise, as stated in In re Marzocchi, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971),

> As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support...it is incumbent upon the Patent Office, whenever a rejection on this basis is made [§ 112, first paragraph, enablement rejection], to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

Respecting both rejections, "the only matter to be determined is the reasonableness of the Patent Office's doubts". In re Gardner, 475 F.2d 1389, 1392, 177 USPQ 396, 398 (CCPA 1973).

In questioning the utility and enablement of appellants' disclosure, the examiner's Answer is long on opinion but short on facts. The examiner states that the asserted utility "would not be

believable on its face" and further expresses the belief or contention that evidence provided in the specification is insufficient to prove the utility of the invention. Conspicuous by its absence from the Answer, however, is a line of reasoning or the presentation of acceptable evidence "which is inconsistent with the contested statement" respecting utility and "how to use". Accordingly, we hold that the examiner has not established a prima facie case of lack of utility or lack of enablement.

We observe that, within reason, a patent applicant may be his own lexicographer. Here, the specification and claims make clear that appellants' vaccine contains essentially pure protein "e" "wherein the protein elicits a protective immune response in a mammalian host" [emphasis added]. Appellants' vaccine need not necessarily confer complete and long-lasting immunity. See the instant specification, pages 23 and 26. Contrast the more stringent definition of vaccine in In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993), namely, a "material which induces an organism to acquire immunity against disease" [emphasis added]. Taking into account the meaning of "vaccine", as that term is used by appellants in their specification and claims, we have no doubt that the examiner has not established a prima facie case of lack of utility or lack of enablement. Again, "vaccine" for appellants' purposes is based on a less stringent definition than the "vaccine" at issue in In re Wright, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993).

Even assuming arguendo that the examiner had established a prima facie case under 35 USC 101 and 35 USC 112, first paragraph, nevertheless, we agree with appellants that rebuttal evidence in the specification, the declaration of Green and Zlotnick, and the declaration of Dr. Arnold L. Smith would be sufficient to rebut any such prima facie case. As correctly pointed out by appellants, for non- typable Haemophilus influenzae, there is no accepted animal model from which reliable data for active immunization can be obtained. Where, as here, reliable active immunization data cannot be obtained, it is scientifically appropriate to rely on in vitro studies demonstrating bactericidal activity, together with passive immunization studies in infant rats, which are accepted as an animal model for such studies.

At pages 50-56 of the specification, appellants demonstrate that anti-protein "e" polyclonal rabbit antisera were able to kill nontypable H. influenzae in an in vitro bactericidal assay system. These data are not contested by the examiner. At paragraph 4 of their declaration, Green and Zlotnick establish that infant rats passively immunized with anti-protein "e" polyclonal rabbit antisera were protected against H. influenzae. Again, these data are not contested by the examiner. We are of the firm conviction, particularly in light of the Smith declaration, that the combination of bactericidal assays and passive immunization studies serves as the best, and commonly accepted, set of models for indicating that the

claimed vaccine and method of immunizing against Haemophilus influenzae will be effective in the manner disclosed by appellants in their specification. The examiner's opinion to the contrary is just that, opinion, which the examiner erroneously substitutes for that of an expert in the art. Cf. In re Zeidler, 682 F.2d 961, 967, 215 USPQ 490, 494 (CCPA 1982) (board erroneously substituted its judgment for that of an established expert in the art).

CONCLUSION

For these reasons, we do not sustain the examiner's non-prior art rejections. Accordingly, the examiner's decision refusing to allow all of the appealed claims is reversed.

REVERSED

FRED E. McKELVEY, Chief)
Administrative Patent Judge)
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SHERMAN D. WINTERS)
Administrative Patent Judge)
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)
TEDDY S. GRON)
Administrative Patent Judge)

BOARD OF PATENT APPEALS AND INTERFERENCES

Appeal No. 94-1618
Application 07/491,466

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